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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,678

01/24/2006

Hiroshi Nakamura

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EXAMINER

MORRIS, PATRICIA L

ART UNIT

PAPER NUMBER

1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/565,678

Applicant(s)

NAKAMURA ET AL.

Examiner

Patricia L. Morris

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 4-6 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-3, 7, 9 and 10 are under consideration in this application.

Claims 4-6 and 8 are held withdrawn from consideration as being drawn to nonelected subject matter. 37 CFR 1.142(b).

#### ***Election/Restrictions***

Applicant's election with traverse of Group I (Claims 1-3) and Group VI (Claims 7, 9 and 10) in the reply filed on December 7, 2006 is acknowledged. The traversal is on the ground(s) that the essential feature of the present invention lies in the process. This is not found persuasive because for the reasons clearly set forth in the record. Applicants' claims 1-3 are drawn to compounds only. Further, applicants admit in the instant response that the instant compounds have already been patented in US 7,074,816. Hence, applicants' admission is evidence that the instant compounds fail to make any contribution to the prior art.

It is too burdensome for the examiner to search all of the previously noted searches in their respective, completely divergent, areas for the non-elected subject matter, as well, in the limited time provided to search one invention.

The requirement is still deemed proper and is therefore maintained.

This application has been examined to the extent readable on the elected compounds wherein R<sub>b</sub> represents (optionally substituted) pyridyl and A and R<sub>c</sub> as set forth in claim 1, exclusively.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nakamura et al.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Nakamura et al. specifically disclose the instant compounds and process. Note the examples 1-35, etc., therein. Also, note claim 1 therein. Hence, the instant compounds and process are disclosed therein.

Claim 1 is rejected under 35 U.S.C. 103 (a), (b) and/or (e) as being anticipated by Okamoto et al. (PNAS, 2004, 101 (21), 7931-7936), Novello et al. (US 3,963,731) and Browne (CA 84:59317).

Okamoto et al. specifically recite the instant compound wherein A is 2-cyanopyridin-4-yl, R<sub>b</sub> is pyridyl and R<sub>c</sub> is hydrogen. Note compound b in Figure 1 therein.

Novello et al. disclose the instant compound wherein A is 1-oxido-4-pyridinyl, R<sub>b</sub> is 4-pyridyl and R<sub>c</sub> is hydrogen. Note example 9 therein.

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Browne et al. disclose the instant compound wherein A is 1-oxido-4-pyridinyl, R<sub>b</sub> is 1-oxido-3-pyridinyl and R<sub>c</sub> is hydrogen. Note RN 59282-65-4 therein.

Hence, the instant compounds are deemed to be anticipated therefrom.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakuma et al.

Nakuma et al. generically embrace the instant compounds and process. Note the compounds of formula (I) therein. Also, note claims 1, 7 and 8 therein.

It is believed that one having ordinary skill in the art would have found the claimed compounds prima facie obvious, since they are generically embraced by the disclosed formula;

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In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also In re Malagari, 499 F.2d 1297, 182 USPQ 549 (CCPA 1974); In re Lemin, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960). The requisite motivation for arriving at the claimed compounds stems from the fact that they fall within the generic class of compounds disclosed by Nakuma et al. Accordingly, one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims, with the expectation that each of them would be suitable as intermediates.

It is believed well settled that a reference may be relied upon for all that it would have reasonably conveyed to one having ordinary skill in the art. In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Lamberti, 545 F.2d 747, 192 USPQ 278 (CCPA 1976); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Susi, *supra*.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 7 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The expressions “optionally substituted”, “substituted” and “Rc represents a group which makes....removed by acid” are employed with considerable abandon throughout claims 1, 2, 7 and 9 with no indication given as to what the substituents or any group which can be removed by acid really are.

One should be able, from a reading of the claims, to determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

***The nature of the invention***

The nature of the invention is the preparation of compounds.

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***State of the Prior Art***

Substituents and other unknown groups for  $R_c$  can have very different properties.

Substituents etc., tend to convert from less stable to more stable forms. No method exists to predict what substituent or other form will work with any significant certainty. Compounds can convert from one form to another during the manufacturing process of a pharmaceutical drug and will change the pharmacological affects of the drug. This is why it is important to monitor the compounds during manufacture of the drug to see if it persists during manufacture.

***The amount of direction or guidance and the presence or absence of working examples***

The specification fails to describe any substituents and any groups for  $R_c$ . Substituents often change into other forms during drug manufacture. Based on the unpredictability in the art, applicants are not entitled to any and all unknown substituents or the variables  $R_c$ .

The written description is considered inadequate here in the specification. Conception of the intended substituents and forms should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

***The breadth of the claims***

The breadth of the claims are drawn to all forms in addition to the instant compounds.



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***The quantity of experimentation needed***

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the compounds and their unknown other forms being claimed.

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant other forms are enabled by the instant application.

Genentech Inc v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001, states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and [p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expressions “optionally substituted”, “substituted” and “R<sub>c</sub> represents.....removed by acid” in claims 1, 2, 7 and 9 are indefinite.

Claim 7 fails to clearly claim what is intended by applicants since it fails to recite the reagents and reaction conditions such as solvents, temperature, etc. What is meant by aimed

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product? What is the nitrilization agent? Nitrilization is an obvious process under 35 U.S.C.

103.

The claims measure the invention. United Carbon Co. v. Binney & Smith., 55 USPQ 381 at 384, col. 1, end of 1<sup>st</sup> paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in *Lockheed Aircraft Corp. v. United States*, 193 USPQ 449, "Claims measure invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": *In re Priest*, 199 USPQ 11, at 15.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-3, 7, 9 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 7 and 8 of U.S. Patent No. 7,074,816. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds and process are disclosed therein. Further, applicants admit that that the instant compounds have already been patented.

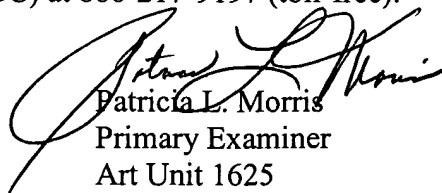
***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia L. Morris  
Primary Examiner  
Art Unit 1625

plm  
January 22, 2007